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Ships and marine technology — Risk assessment on anti-fouling systems on ships —

Part 2: Marine environmental risk assessment method for anti-fouling systems on ships using biocidally active substances

Navires et technologie maritime — Évaluation des risques pour les systèmes antisalissure sur les navires —
Partie 2: Méthode d'évaluation des risques environnementaux maritimes pour les systèmes antisalissure sur les navires utilisant des substances actives biocides

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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The committee responsible for this document is ISO/TC 8, *Ships and marine technology*, SC 2, *Marine environment protection*.

ISO 13073 consists of the following parts, under the general title *Marine environment protection — Risk assessment on anti-fouling systems on ships*:

- *Part 1: Marine environmental risk assessment method of biocidally active substances used for anti-fouling systems on ships*
- *Part 2: Marine environmental risk assessment method for anti-fouling systems on ships using biocidally active substances*
- *Part 3: Human health risk assessment for the application and removal of anti-fouling systems (under development)*

Introduction

The attachment of fouling organisms such as barnacles and algae on the submerged parts of a ship's hull increases the propulsive resistance of the hull against water, leading to increased fuel consumption and accidental introduction of non-indigenous species to a foreign marine environment, which may cause significant and harmful changes. As a means of preventing such circumstances, an anti-fouling system that relies on biocidally active substances (e.g. anti-fouling paint) to prevent attachment of fouling organisms can be applied onto the hull of the ship. The harmful effects of organotin compounds used as biocides (historically used in anti-fouling paint) on marine organisms and human health have been of global concern. To prevent the continued use of these compounds, a legally-binding international framework regulating the use of anti-fouling systems containing harmful substances was enacted by the International Maritime Organization (IMO). Consequently, the International Convention on the Control of Harmful Anti-fouling Systems on Ships (the AFS Convention) was adopted at the IMO diplomatic conference held in London in October 2001, and entered into force in September 2008.

The Convention envisages handling various harmful anti-fouling systems within its framework and lays out a process by which anti-fouling systems can be risk assessed. Annexes 2 and 3 of the Convention include the list of information needed to determine whether an anti-fouling system is harmful to the environment and should be restricted from use on ships, but a marine environmental risk assessment method for making this decision is not provided. Furthermore, Resolution 3, adopted by IMO along with the AFS Convention recommends that contracting Parties continue to work in appropriate international fora for harmonization of test methods and assessment methodologies, and performance standards for anti-fouling systems containing biocidally active substance(s).

Based on this, there is a global need for an international method for conducting scientific environmental risk assessments for anti-fouling systems substituting organotin-based anti-fouling systems. This part of 13073 allows a pragmatic approach to introducing systems (i.e., self-regulation or approval systems) in countries where either no system exists, or a less developed system is in place and would allow such countries to improve protection of the aquatic environment.

Ships and marine technology — Risk assessment on anti-fouling systems on ships —

Part 2: Marine environmental risk assessment method for anti-fouling systems on ships using biocidally active substances

1 Scope

This part of ISO 13073 specifies a risk assessment method that protects the marine environment from the potential negative impacts of anti-fouling systems intentionally using biocidally active substances applied to a ship during its service life. This method can also be modified for use in freshwater environments.

This part of ISO 13073 does not provide specific test methods for evaluating the hazards nor recommends usage restrictions for certain anti-fouling systems. It also does not provide an efficacy-evaluation method of the anti-fouling system using a specific substance.

The following uses of anti-fouling systems are also not covered by this part of ISO 13073:

— use at the application and removal stages, during new building, vessel maintenance and repair or ship recycling;

— use of systems intended to control harmful aquatic organisms and pathogens in ships' ballast water and sediments according to the International Convention for The Control and Management of Ships' Ballast Water and Sediments, 2004;

— use of anti-fouling systems applied to fishing gear, buoys and floats used for the purpose of fishing, and to equipment used in fisheries and aquaculture (nets/cages, etc.); and

— test patches of anti-fouling systems on ships and small panels for the purposes of research and development of anti-fouling systems.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13073-1:2012, *Ships and marine technology — Risk assessment on anti-fouling systems on ships — Part 1: Marine environmental risk assessment method of biocidally active substances used for anti-fouling systems on ships*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13073-1 and the following apply.

3.1
substance of concern
an intentionally added non-biocidal substance which is classified as acute or long-term hazard category 1 or 2 for "hazardous to aquatic environment" under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009) and is released to the marine environment based on emission scenario(s)

4 Application

4.1 General

Risk assessment, as defined in this part of ISO 13073 and ISO 13073-1, is conducted for the protection of the marine environment. In order to confirm the risk of a biocidally active substance in an anti-fouling system, a risk assessment according to this part of ISO 13073 shall be conducted. In this part, the risk assessment is conducted for anti-fouling systems using biocidally active substances which have undergone the risk assessment given in ISO 13073-1. This assessment will identify the risk categorization of the anti-fouling system to allow decisions to be made on the use of this anti-fouling system in a certain environment.

This part of ISO 13073 provides a minimum guideline for the following uses:

— regulation of anti-fouling systems by government organizations;

— self-regulation or approval systems carried out for industry by industrial organizations or other third parties; and

— evaluations conducted for product development by the industry.

This part of ISO 13073 will enable the quantitative characterization of the environmental risk posed by an anti-fouling system on the marine environment and determine whether the environmental risk of the system is acceptable.

This part of ISO 13073 could be modified for assessing risk to freshwater environments such as rivers and lakes. Special attention should be given to defining the emission scenarios required for freshwater areas, and particular care should be taken to consider the effects on the species found in those environments.

4.2 Application considerations

This part of ISO 13073 provides a method for quantifying the marine (and freshwater, where necessary) environmental risk posed by an anti-fouling system, but does not directly regulate or approve the use or commercialization of the anti-fouling system. As a result of risk characterization of an anti-fouling system designated in Clause 8, a categorization into "possible high risk to the marine environment" does not necessarily mean a prohibition of its use. It may be accepted for use under certain conditions which demonstrates a reduction in the environmental exposure such as by use of additional mitigation measures, by refinement of the exposure assessment or by continuous monitoring of the relevant environment.

The risk assessment of the biocidally active substances that are in an anti-fouling system shall be conducted in accordance with ISO 13073-1 prior to making the assessment using this part of ISO 13073. Substances categorized as "low risk" or "relatively low risk" to the marine environment through the ISO 13073-1 risk assessment should generally be used in this risk assessment. In exceptional cases, special care shall be taken with the description designated in 5.1 when substances categorized as "risk of high concern" to the marine environment through the ISO 13073-1 risk assessment are used.

All data submitted by an applicant are, and shall remain, the property of the applicant under this part of ISO 13073. These data shall not be made available to other applicants without prior written approval from the owner of the data.

4.3 Structure and procedure of environmental risk assessment

The environmental risk assessment procedure consists of four components: review of the risk of biocidally active substance under ISO 13073-1, exposure assessment, representation of result of the hazard assessment, and risk characterization. The ratio of the predicted environment concentration (*PEC*) to the predicted no-effect concentration (*PNEC*) (*PEC/PNEC*) is used as a quantitative index for the risk assessment. The procedure is summarized in Figure 1.

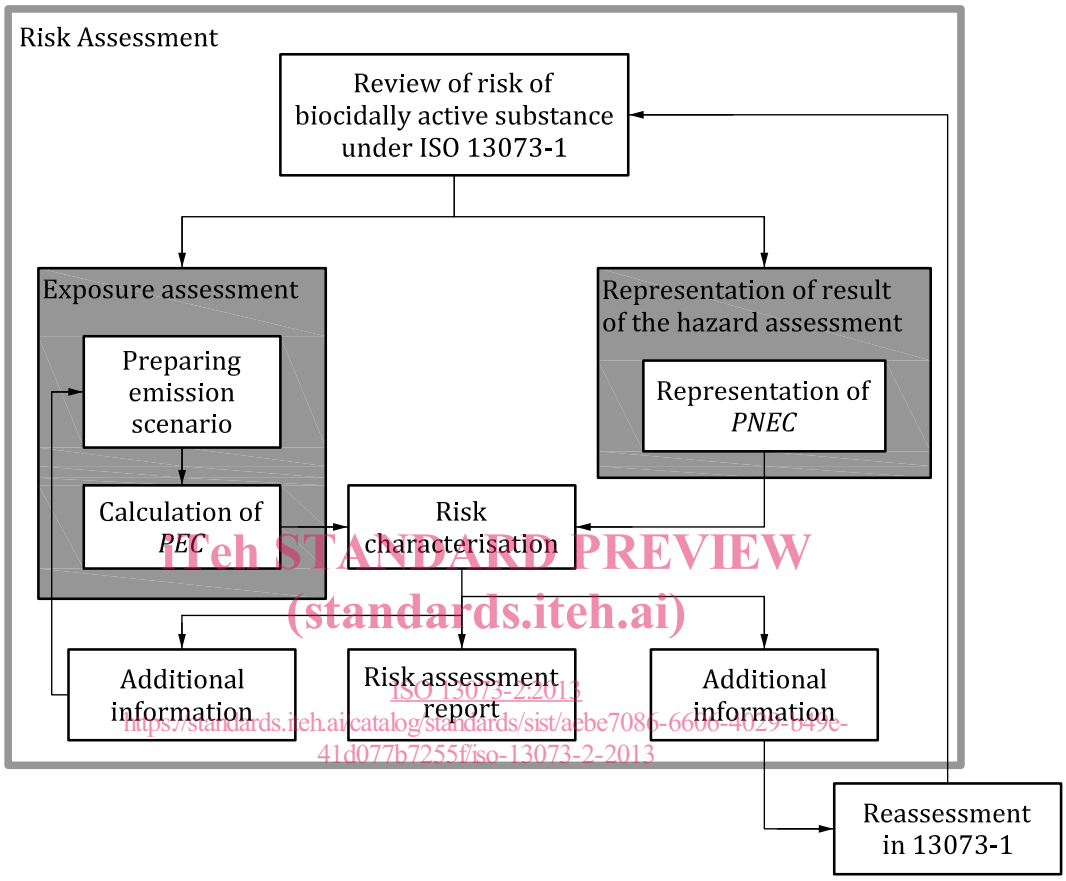

Figure 1 — Composition and schematic procedure of environmental risk assessment for anti-fouling systems on ships using biocidally active substances

5 Review of the risk of a biocidally active substance when used in the anti-fouling system

5.1 General

It shall be confirmed in accordance with the procedures in ISO 13073-1 that biocidally active substances intentionally added to an anti-fouling system are characterized as “low risk” or “relatively low risk” to the marine environment.

If any of the biocidally active substances is to be regarded as a “risk of high concern”, the use of the anti-fouling system may be considered for certain types of marine environments as described in 5.3, and this may result in restrictions on the use of such products or requirements for carrying out environmental monitoring. Such restrictions may (or may not) include restrictions in the environment where such products may be used, restrictions on the allowed maximum release rate, restrictions on the time period during which such products may be used (e.g. particular times of year), or restrictions in the type or size of the application area such as use in niche areas.